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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/456,278	12/07/1999	Jesus Miranda	P24,540 USA	6233

7590 02/23/2004

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EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/456,278	MIRANDA ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- Th MAILING DATE of this communication app ars on the cov r sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/13/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *2,4,5 and 8-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 6, 7, 27-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request under 1.114, request for extension of time and IDS, both filed 11/13/2003.

Claims 1, 3, 6, 7, and 27-38 are included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 6, 7, 27-31, 34, 35, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,603,947 ('947) in view of US 5,914,282 ('282).

Applicants' claims 1 and 27 read as follows:

A transdermal patch comprising the following layers:

- An impermeable backing layer,
- Silicone adhesive layer containing the drug,
- Acrylic adhesive layer, and
- Removable release liner.

US '947 discloses a device for providing nicotine replacement therapy transdermally. The device comprises an impermeable backing, matrix layer containing nicotine in silicone adhesive, an adhesive layer to affix the device to the skin and a release liner (abstract; col.2, lines1 6-20; col.3, lines1 5- 1 8; col.5, lines 51 –53; col.6, lines1 -8, 40-45).

However, the US '947 does not teach the adhesive layer as acrylic adhesive as in component (c) of claims 1, 27, 28 and 30, or the components of the acrylic adhesive as claimed in claims 7 and 38. The reference does not teach the thickness of the adhesive layer as in claim 31.

The claimed thickness does not impart patentability to the composition claims, absent evidence to the contrary.

US '282 teaches a pressure sensitive adhesive useful for medical dressings and has the advantages of ease of manufacture, excellent safety history profile, high shear

strength, low coast and chemical stability (abstract; col.1, lines 7-12; col.3, lines 48-52). The adhesive comprises a blend of two components at the ratio of 10:90 to 90:10, and the first component comprising iso octyl acrylate and ethylhexyl acrylate (col.3, lines 35, 63-64; col.7, lines 17-20).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal patch comprising nicotine in a silicone matrix and having an adhesive layer on the skin facing surface as disclosed by US '947, and replace the adhesive layer by the acrylic adhesive layer disclosed in US '282, motivated by the teaching of US '282 that the disclosed acrylic pressure sensitive adhesive has the advantages of ease of manufacture, excellent safety history profile, high shear strength, low coast and chemical stability, with reasonable expectation of having a drug delivery device comprises nicotine and silicone matrix that is covered by acrylic adhesive skin contact layer that is safe and stable for treating drug dependency with success.

4. Claims 3, 32, 33, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '947 in view of US '282 as applied to claims 1, 6, 7, 27-31, 34, 35, 37 and 38 above, and further in view of US 5,316,759 ('759).

The teachings of US '947 in view of US '282 are discussed above.

However, the references in combination do not teach the drug as a combination of nicotine and mecamylamine as claimed in claims 3, 32 and 33, or that the amount of

the drug is sufficient to provide administration of the drug for a period up to about 72 hours as claimed in claim 36.

US '759 is teaching the transdermal drug delivery of nicotine and mecamylamine combined in a single dose in the form of a patch, claims 32 and 33, so that the administration of the drug and its antagonist together in the same patch will not allow the drug user or abuser to separate the desired portion of the composition, i.e. the drug, from the antagonist. The patch comprises an impermeable backing; reservoir containing silicone polymer matrix and the drugs; and releasable liner. The patch provides a steady rate of delivery of 1-4 mg per hour of nicotine and 0.5-1 mg per hour of mecamylamine, same amounts claimed in claim 3. See the abstract; col.3, lines 26-30; col.4, col.5, lines 6-9; col.6, lines 50-64; col.8, lines 6-8, 29-32, 43-50, 65-67; col.9, lines 19-41.

It is expected to the transdermal patch disclosed by US '759 that contains the same amounts of the nicotine and mecamylamine as that claimed by applicant in claim 3 to provide administration of the drug for a period up to about 72 hours as claimed in claim 36.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal patch for administering volatile drugs comprising backing, silicone adhesive layer containing the drug, acrylic adhesive layer and removable release liner as disclosed by US '947 in view of US '282, and replace the nicotine by both nicotine and its antagonist mecamylamine in the drug containing layer as taught by US '759, motivated by the teaching of US '759 that the administration of the drug and its antagonist together in the same patch will not allow the drug user or

abuser to separate the desired portion of the composition, i.e. the drug, from the antagonist, with reasonable expectation of treating patients suffering from nicotine dependency using the delivered patch with success.

Response to Arguments

5. Applicant's arguments with respect to claims 1, 3, 6, 7, 27 have been considered but are moot in view of the new ground(s) of rejection.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615

ISIS GHALI
PATENT EXAMINER

Isis Ghali